

# Minutes – ENCePP Steering Group meeting

16 September 2025, 15:00 – 16:00

**Chairs:** Helga Gardarsdottir (Utrecht University) & Catherine Cohet (EMA)

**ENCePP SG members:** Alejandro Arana, Annalisa Landi, Christos Kontogiorgis, Frauke Naumann-Winter, Gianmario Candore, Gianluca Trifirò, Iryna Vlasenko, Laura Pizzi, Marco Tuccori, Nadia Amaouche, Thomas Goedecke, Vera Ehrenstein,

**EMA:** Patrice Verpillat, Julianna Fogd

**Excused:** Arnold Chan, Carla Torre, Hedvig Marie Egeland Nordeng, Melissa Kampman

	Topic	Speaker(s)	Objective	Indicative timing
1.	Welcome & adoption of the agenda	Helga & Catherine	Endorsement	5'
2.	Criteria for honorary ENCePP membership	SG volunteer(s)	Discussion/ decision	10'
3.	ENCePP Plenary: agenda topics, incl. proposals for external speakers	All SG members	Discussion/ preliminary decision	20'
4.	WGs/SIGs – quick update on revised mandates from the groups	Catherine	Information	10'
5.	ENCePP transparency strategy (e.g., protocol templates, registration of studies)	Helga	Discussion	10'
6.	Next SG meeting & A.O.B	All SG members		5'

## 1. Welcome

C. Cohet and H. Gardasdottir welcomed the participants and introduced the agenda.

## 2. Criteria for honorary ENCePP membership

H. Gardasdottir reminded the proposal for an honorary ENCePP membership for individuals who significantly contribute(ed) to ENCePP over the years, or no longer/not belonging to an institution/network (e.g., retired), to provide an opportunity to support the delivery of the workplan, e.g. by joining WGs/SIGs. The SG agreed that there should be clear criteria for the selection process, similarly, for example, to the [FISPE](#) criteria. These may include: seniority, former substantial contribution to ENCePP (e.g., active participation in at least one (or 2) WGs or SIGs, contribution to the ENCePP Guide, etc), evidence of leadership in pharmacovigilance and pharmacoepidemiology, and motivation.

**ACTION** – One (or 2) SG members to take the lead on providing a final brief list of nomination criteria. The goal is to make an announcement for the first nominee(s) at the ENCePP Plenary on December 1<sup>st</sup>.

### **3. ENCePP Plenary: agenda topics, incl. proposals for external speakers**

Potential topics for the December Plenary have been proposed by SG members, EMA, and ENCePP partners who registered for the Plenary. They include: progress update on the new WGs/SIGs; update on EU/international regulatory/non-regulatory guidance (ICH, EMA: RWE, external controls, PED), EHDS, and pharmaceutical legislation; DARWIN EU update; vaccines/vaccination hot topics. Methodology sessions: target trial emulation/estimands frameworks, pragmatic trials.

**ACTION** – EMA to share draft agenda for the Plenary with SG for input/comments.

### **4. WGs/SIGs – quick update on revised mandates from the groups**

After the June SG meeting, the WGs/SIGs chairs addressed the comments of the SG. C. Cohet briefly highlighted key updates to their draft mandates (still waiting for updates from two groups). It was agreed that the objectives will be published on the ENCePP website in a few weeks. The WGs/SIGs chairs will be invited to give an update on their mandates and deliverables at the December Plenary.

### **5. ENCePP transparency strategy (e.g., protocol templates, registration of studies)**

H. Gardasdottir raised the importance for ENCePP to contribute increasing awareness of registering studies on public registers such as the [HMA-EMA Catalogue of real-world data studies](#) and other available registers, regardless of the type of study. This is in line with ENCePP working principles which promote transparency and scientific independence in conduct of non-interventional studies.

### **6. Next SG meeting & A.O.B**

No further meetings are planned before the ENCePP Plenary, agenda topics and AOBs will be discussed in writing.